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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,825	08/27/2003	Jian Ni	1488.131000C/EKS/EJH	3624

28730 7590 04/10/2006

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/648,825	Applicant(s) NI ET AL.	
	Examiner Claire M. Kaufman	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-285 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 78-181 is/are allowed.
- 6) ☒ Claim(s) 182-285 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/3/04, 7/23/04, 6/15/05, 11/04/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Death domain containing receptor 5 antibodies and methods of use.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 182, 196, 210, 224, 238, 250, 262, 274 and dependent claims 183-195, 197-209, 211-223, 225-237, 239-249, 251-261, 263-273 and 275-285 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 182, 196, 210, 224, 238, 250, 262 and 274 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is: an agonist antibody, *i.e.*, an antibody that induces apoptosis upon binding a DR5 receptor expressed on a cell. The method requires inducing apoptosis in DR5-expressing cells and comprises the use of an antibody that binds DR5. However, the method cannot be accomplished if the antibody is not an agonist antibody. An agonist antibody is an essential element for the method.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pregrant Publications of Holtzman (2002/0048785, 2002/0160446, 2003/0125540) disclose Tango 63 and splice variants thereof which are the same as or share high identity with to SEQ ID NO:2 of the instant application. Antibodies and methods of using antibodies are also disclosed. However, the earliest possible effective filing date of the applications is 4/16/97; and, therefore, none of the Holtzman documents are available as prior

Art Unit: 1646

art. US Pregrant Publication 2004/0009552 teaches DR5, which is identical to SEQ ID NO:2 of the instant application with the exception of two amino acid substitutions: position 32 and 410, and agonist antibodies which bind DR5 as well as methods of inducing apoptosis and treating cancer. However, this application has an effective filing date after the effective filing date of the instant application and is, therefore, not available as prior art. US 6,072,047 (AK1 in IDS of 3/3/04) teaches TRAIL-R, which is identical to SEQ ID NO:2 of the instant application with the exception of a 29 amino acid insert at position 182, as well as agonist antibodies. This application is not available as prior art.

Alternative Names

DR5 is also known as Apo-2, TRAIL-R, death receptor-5, TRAIL-R2, TRAIL-2, Trick2, Killer, Tango63e and TR6.

Conclusion

Claims 78-181 are allowed.

Claims 182, 196, 210, 224, 238, 250, 262 and 274 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 183-195, 197-209, 211-223, 225-237, 239-249, 251-261, 263-273 and 275-285 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

A telephone call was made to Elizabeth Haanes on March 27, 2006, requesting an Examiner's amendment to overcome the rejection of claims under 35 USC 112, second paragraph, but did not result in approval of an amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873.

Art Unit: 1646

Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.

A handwritten signature in cursive script, appearing to read 'Claire M. Kaufman', followed by a horizontal line.

April 6, 2006